

OBJECTIVES: A once-weekly formulation of exenatide (EQW) received positive opinion from the EMA in April 2011 for the treatment of type 2 diabetes. No head-to-head study of EQW and liraglutide 1.2mg once-daily (the dose recommended by NICE) has been conducted therefore a network meta-analysis to compare EQW to liraglutide 1.2mg in terms of effect on HbA1c was performed. **METHODS:** A systematic review was conducted to identify randomized controlled trials of EQW and liraglutide (1.2mg and 1.8mg) of 24 weeks or more, and the common comparators insulin glargine and exenatide bid to allow a network meta-analysis. Additionally, the manufacturing companies were asked to provide any unpublished data from studies meeting the criteria. 22 studies including 10,816 patients met our inclusion criteria. Treatments were compared in terms of mean difference in HbA1c relative to placebo. Additionally, EQW was compared to both doses of liraglutide, and liraglutide 1.2mg was compared to liraglutide 1.8mg. **RESULTS:** Results from random effects models controlling for baseline HbA1c are presented. Analysis of change in HbA1c produced estimated mean differences relative to placebo of -1.15% (95% CI -1.31, -1.00) for EQW, -1.01% (95% CI -1.18, -0.85) for liraglutide 1.2mg, and -1.18% (95% CI -1.32%, -1.04%) for liraglutide 1.8mg. The comparison of EQW to liraglutide 1.2mg and liraglutide 1.8mg showed a mean difference (95% CI) of -0.14% (-0.34, 0.06) and 0.03% (-0.14, 0.18) respectively. Liraglutide 1.2mg compared to liraglutide 1.8mg showed a mean difference in HbA1c of 0.17% (0.02, 0.30). Results were consistent when controlling for use of background antihyperglycemic medications. **CONCLUSIONS:** Our analysis suggests EQW and both doses of liraglutide have robust and similar efficacy with respect to lowering of HbA1c. Further analysis is warranted to investigate the inconsistency between the direct and indirect evidence with respect to the comparison of EQW to liraglutide 1.8mg.

PDB9

WEIGHT LOSS, INDEPENDENT OF DRUG CLASS, PREDICTS HBA1C GOAL ATTAINMENT IN PATIENTS 65 YEARS AND OLDER IN A REAL-WORLD SETTING

McAdam-Marx C¹, Brixner D¹, Ye X¹, Unni S¹, Mukherjee J²

¹University of Utah, Salt Lake City, UT, USA, ²Bristol-Myers Squibb, Wallingford, CT, USA

OBJECTIVES: To evaluate weight change and glycemic control in patients age 65+ with type 2 diabetes (T2DM) in a usual-care setting. **METHODS:** Treatment naïve patients age 65+ years with T2DM and a prescription (index date) for a sulfonylurea (SU), metformin (MET), thiazolidinedione (TZD), GLP-1 agonist (GLP-1), or DPP-4 inhibitor (DPP-4) were identified in an electronic medical record database from 1/1/2000 to 6/30/2010. HbA1c <7% or ≥7% and weight gain or loss of ≥3% were assessed 1 year post-index. Logistic regression identified the likelihood of weight loss and attaining HbA1c goal by antidiabetic drug class, controlling for baseline HbA1c and weight, and for weight change for HbA1c goal attainment. **RESULTS:** Of 12,473 patients, 46.4% were male and the mean age was 71.7 (±3.9) years. At baseline 26.7% had HbA1c <7.0%; mean weight 86.8 (±18.7) kg. Breakdown by drug class was: SU - 31.0%, MET - 55.0%, TZD - 11.6%, DPP-4 - 1.9%, and GLP-1 - 0.6%. At 1 year, 34.8% lost ≥3% of body weight and 46.5% had an HbA1c <7.0%. In logistic regression analyses, MET and DPP-4 (OR 1.4 and 1.36; p<.05) were associated weight loss relative to SU, TZDs were negatively associated with weight loss (OR 0.86; p<.05), and GLP-1 did not differ (OR 1.55; p=0.08). Patients who lost weight were 2.26 times as likely as those who did not to attain HbA1c goal (p<.05). Drug class was not associated with HbA1c goal attainment (p>0.05). **CONCLUSIONS:** In patients with T2DM age 65+, those who lost weight were more likely to attain HbA1c goal than those who did not. MET and DPP-4 were associated with weight loss vs. SU, but drug class was not associated with HbA1c goal attainment. These findings support guideline recommendations to consider weight-effect properties of antidiabetics in treating T2DM with data specific to patients age 65+.

PDB10

ACHIEVING TARGET GOALS IN PATIENTS WITH T2DM TREATED WITH EXENATIDE ONCE WEEKLY OR INSULIN GLARGINE: A RETROSPECTIVE ANALYSIS OF THE NUMBER-NEEDED-TO-TREAT

Bruhn D¹, Han J², Meloni A², DeYoung MB², Anderson PW¹

¹Eli Lilly and Company, Indianapolis, IN, USA, ²Amylin Pharmaceuticals, Inc., San Diego, CA, USA

OBJECTIVES: This post hoc analysis analyzed the number of patients needed to be treated (NNT) with the GLP-1 receptor agonist exenatide once weekly (ExQW) vs titrated insulin glargine (IG) over 26 weeks to allow one additional patient to achieve single or combined recommended treatment goals. **METHODS:** Data from the DURATION-3 trial was analyzed retrospectively. Treatment targets included: 1) glycaemia (HbA1c ≤6.5% or fasting plasma glucose (FPG) <7 mmol/L); 2) systolic blood pressure (SBP <130 mmHg); 3) low-density lipoprotein cholesterol (LDL <2.59 mmol/L); and 4) weight loss or maintenance. Hypoglycemic events were also assessed. NNT was calculated for the entire intent-to-treat (ITT) population (ExQW n=233, IG n=223) and for subpopulations of patients on different background therapies (metformin ± sulfonylurea). NNT was calculated using 1/Absolute Risk Reduction (percent of patients reaching goal in the ExQW treatment arm - percent of patients reaching goal in the IG treatment arm). **RESULTS:** Baseline mean characteristics were similar for both treatment groups: 45-48% women, age 58 years, HbA1c 8.3%, and body mass index 32 kg/m². Regardless of background therapy, 8 patients would need to be treated with ExQW in place of IG for 26 weeks to allow one additional patient to attain the HbA1c goal. Five patients (ITT) would need to be treated with ExQW vs IG to allow one additional patient to attain the HbA1c goal with weight control and the absence of hypoglycaemia. Furthermore, 14 patients (ITT) would need to be treated with ExQW versus IG to allow one additional patient to reach combined HbA1c, SBP, and LDL goals. Only the FPG goal favored insulin use with an NNT of -8 (ITT). Minor differences in the NNT values were observed between subpopulations for most goals. **CONCLUSIONS:** Both ExQW and IG treated

patients achieved therapeutic target goals. In this post hoc analysis the NNT results favored ExQW for most goals.

PDB11

GLYCEMIC OUTCOMES AMONG PATIENTS RECEIVING EXENATIDE BID OR LIRAGLUTIDE FOR TYPE 2 DIABETES IN CLINICAL PRACTICE: A RETROSPECTIVE ANALYSIS OF THE GE CENTRICITY EMR DATA

Best JH¹, Wintle M¹, Saunders WB¹, DeYoung MB¹, Blickensderfer A¹, Maggs D¹

¹Amylin Pharmaceuticals, Inc., San Diego, CA, USA, ²GE Healthcare, Charlotte, NC, USA

OBJECTIVES: Exenatide twice daily (exenatide) and liraglutide once daily, GLP-1 receptor agonists, have demonstrated improvements in glycemic outcomes for patients with type 2 diabetes (T2D) in randomized clinical trials. We evaluated A1c outcomes for patients initiating exenatide or liraglutide in a real-world setting. **METHODS:** This retrospective cohort study used data from the Medical Quality Improvement Consortium of ambulatory medical practices that use Centricity Office from GE Healthcare IT as their electronic medical record. Patients with T2D receiving a prescription between June 2005 and May 2011 were identified (exenatide=61,485; liraglutide=9,316). Baseline A1c measures were documented from 45 days prior to 15 days after initiating exenatide or liraglutide with follow-up measures documented at 6 months+45 days. An ANCOVA model including baseline A1c, age, gender, concomitant glucose-lowering medications, and modified Charlson Comorbidity Index (CCI) was used to estimate least squares mean A1c. **RESULTS:** Mean(SD) age was 55(12) and 55(12), CCI 2.0(1.3) and 2.1(1.3), % male 41% and 42% for exenatide and liraglutide patients, respectively. Baseline BMI was 38.4(7.8) and 37.9(7.7) for exenatide and liraglutide patients, respectively, who had baseline and 6 month BMI data. Of patients not at A1c goal of <7.0% at baseline, the mean(SD) baseline A1c was 8.7(1.4) for exenatide and 8.6(1.3) for liraglutide, and at 6 months was 8.0%(1.6) for exenatide and 7.9%(1.6) for liraglutide; 29.8% of patients receiving exenatide and 30.8% of patients receiving liraglutide achieved <7% A1c goal at 6 months. At baseline, 47% of exenatide patients were prescribed 10 mcg BID daily; 7.7% and 83.9% of liraglutide patients were prescribed 1.2 and 1.8 mg daily, respectively. At 6 months, 66% of exenatide patients were prescribed 10 mcg BID daily; 11.2% and 75.4% were prescribed liraglutide 1.2 and 1.8 mg daily, respectively. **CONCLUSIONS:** In this retrospective cohort study, glycemic outcomes similarly improved for patients initiating exenatide or liraglutide.

PDB12

GLARGINE UTILISATION IN RUSSIA: A PROSPECTIVE STUDY TO EVALUATE PATIENTS SWITCHED FROM NPH INSULIN TO INSULIN GLARGINE COMPARED WITH THOSE MAINTAINED ON NPH

Skudaev S, Verbovaya N

Samara State Medical University, Samara, Russia

OBJECTIVES: The LANTUS Utilisation in RUSSIA Study 2 (LAURUS 2) was an observational study undertaken at 245 sites as a follow-up to the LAURUS study. It evaluated the efficacy of switching patients with type 2 diabetes mellitus (T2DM) from NPH insulin to insulin glargine in real-life clinical practice. **METHODS:** Eligible adult patients had taken NPH and 2 oral antidiabetes drugs (OADs) for ≥ 12 months. During the 12-week study period all patients continued OADs. The active arm included patients whose physicians switched their basal insulin from NPH to glargine. Patients in the control group continued on NPH. Primary end point was change in HbA_{1c}. Secondary end points included changes in fasting blood glucose (FBG) and insulin dose and hypoglycaemic episodes (HEs). **RESULTS:** Data were available for 2395 of the 3000 enrolled patients. Patients had a mean duration of diabetes of 9.3 ± 5.1 y and mean duration of insulin therapy of 2.6 ± 2.6 y. Mean baseline HbA_{1c} was 9.0 ± 1.5 % and 9.2 ± 1.4 % in the NPH and glargine groups, respectively. After 12 weeks, mean HbA_{1c} decreased by 0.6 % and 1.7 % in the NPH and glargine groups, respectively (P <0.001). HbA_{1c} < 7% was attained by 8.4% and 25.8% of patients, respectively. Mean FBG decreased 1.4 ± 1.7 mmol/L and 3.3 ± 2.1 mmol/L, respectively (P <0.001). Mean insulin dose increased in both groups. At baseline, ≥ 1 severe hypoglycaemic episode was reported by 0.4% and 0.7% of NPH and glargine patients, respectively. At 12 weeks, no glargine patients reported severe hypoglycaemia, but 2 (0.8%) NPH patients had at least 1 episode. **CONCLUSIONS:** In this observational study, switching patients with T2DM who were inadequately controlled on NPH to glargine improved glycaemic control with minimal incidence of severe hypoglycaemia.

PDB13

A PROSPECTIVE REGISTRY TO IDENTIFY PATIENTS' CHARACTERISTICS ASSOCIATED WITH ACHIEVING TARGET METABOLIC CONTROL AFTER THREE MONTHS TREATMENT WITH INSULIN GLULISINE IN TYPE 1 AND 2 DIABETES MELLITUS PATIENTS PREVIOUSLY UNCONTROLLED ON BASAL INSULIN AND/OR OTHER ANTI-DIABETIC TREATMENT (API REGISTRY)

Gottesman I¹, Girard M², Shorey S³

¹University of Toronto, Mississauga, ON, Canada, ²Sanofi-Aventis, Laval, QC, Canada,

³Brampton Civic Hospital, Brampton, ON, Canada

OBJECTIVES: Results from Canadian population-based studies show that glycaemic control (HbA_{1c} ≤7.0%) is often not achieved in patients with either type 1 (T1DM) or type 2 (T2DM) diabetes mellitus. The aim of this prospective registry was to identify patient characteristics associated with achieving HbA_{1c} ≤7.0% in a real-life setting 3 months after adding insulin glulisine to previous anti-hyperglycaemic therapies. **METHODS:** The API registry included adult patients with T1DM or T2DM who were receiving basal insulin (± anti-diabetic agents) and still had HbA_{1c} >7%. Patients for whom the treating physician had initiated the addition of insulin glulisine within the month prior to study entry were assessed at baseline and 3 months. Logistic regression using the backward elimination technique was performed to identify the patient characteristics. **RESULTS:** HbA_{1c} was available at